COSMETICS PROGRAMME REVIEW

REVISED REPORT

August 1997

Health Canada

1. ISSUE

To develop an effective and efficient Cosmetics Programme.

2. BACKGROUND

Renewal project M-07 was initiated as part of the Drugs Programme Renewal exercise to review certain aspects of the Cosmetics Programme. As part of this initiative, a discussion paper was prepared to provide recommendations on the most appropriate location for the operation of the existing Cosmetics Programme and to assess the risk of tort liability arising from the current operational programme. The renewal project report M-07 clearly demonstrated the Department's liability for the Cosmetics Programme.

Industry was advised in March 1995 of the Drugs Programme's intention to introduce a fee for cosmetic notification by 1996-1997 to recover the costs of operating the Cosmetics Programme. Preliminary analysis indicated that a fee of $140 per notification would recoup the $300000 annual operating cost of the programme.

In January 1996, the industry association, the Canadian Cosmetic, Toiletry and Fragrance Association (CCTFA) hosted a workshop in Toronto to discuss the Cosmetics Programme as a whole. It was determined that a complete review of the programme needed to be conducted prior to developing the cosmetics cost recovery initiative. At this workshop, efforts to resolve some of the programme issues were made. Sub-groups, with representatives from the Drugs Programme, discussed specific issues such as compliance, programme mandate, programme delivery, etc.

As a result of this workshop, the CCTFA created the Cosmetics Regulatory Review Task Force and worked in cooperation with the Drugs Programme in developing an effective and efficient cosmetics regulatory programme. As part of this proposed new programme, industry will be more involved in administering the regulations and will accept a number of responsibilities which were previously identified as being government's responsibilities.

3. CURRENT LEGISLATION

The current legislation does not provide for a pre-market evaluation of cosmetics. Canadian manufacturers are required to submit a notification to the Drugs Programme within 10 days of first sale. Importers are required to submit their notification prior to importation. The information contained in a notification includes name and address of the manufacturer/distributer, name of product, its form, ingredients and their concentration range, etc. The one page-document provides minimal information on the product. Labels are not required to be submitted with the notification (except where cautionary labelling/adequate directions for use is required by the regulations).

The Cosmetic Regulations to the *Food and Drugs Act* (with the additional requirements of the *Consumer Packaging and Labelling Act and Regulations*, discussed below) is essentially all of the federal legislation pertaining to cosmetics. Only a few ingredients are expressly prohibited by the Regulations, however, the sale of cosmetics containing other ingredients that are considered to represent a health hazard is prohibited by Section 16 of the Act.

The Regulations provide the authority to request evidence of the safety of a cosmetic. If this evidence is not considered sufficient to establish the safety of the product, the Regulations state that the manufacturer is to be notified and the product should not be sold. As no safety data is generally submitted with the notification (none is required by the Regulations) any initial assessment of the acceptability of the product must be based on an assessment of the toxicity of the individual ingredients.

Because labels are not required to be submitted with the notification, it is not possible to determine whether manufacturers have complied with labelling requirements. However, these requirements (product identity, name and address of the manufacturer, net quantity declaration) are not generally issues of safety. An area of contention in the current programme is the use of inappropriate label claims, essentially "drug" claims on cosmetic labels. Claims such as antidandruff, antiperspirant, sun protection, anti-caries, anti-acne are considered to be drug claims and are inappropriate for products sold as cosmetics. Other drug claims such as removes cellulite, restores hair growth, slims thighs are more in the area of "puffery", i.e., the products are unlikely to actually have the actions claimed on the labelling and the manufacturers would be unable to provide the required efficacy data in order to receive the Drug Identification Number (DIN) required to be able to market these products as drugs in compliance with the *Food and Drugs Act and Regulations*. Inappropriate label claims of this type are generally unlikely to represent safety concerns and could be considered to be fraudulent. This then falls under the jurisdiction of the *Consumer Packaging and Labelling Act and Regulations*.

No number analogous to a DIN or a General Proprietary Number (GP) is required to be issued to a manufacturer before a cosmetic is marketed. For that reason, in the customs warehouse or on store shelves it is not possible to determine from package labelling if the manufacturer has complied with Sections 10 and 30 of the *Cosmetic Regulations* and submitted a cosmetic notification.

Manufacturers compliance with this notification requirement seems to be fairly low. In addition, the current post-market surveillance programme does not provide for an effective way to ensure compliance. Industry has complained that little or no action is taken against manufacturers who are not in compliance with the Regulations and is requesting a level playing field. Under the current programme, there is little incentive for manufacturers to comply with the Regulations.

4. PROPOSED FRAMEWORK

This framework has been developed based on recommendations made by the Drugs Programme Reference Group and the CCTFA Task Force on Cosmetics Regulations and has the following attributes.

4.1. Mandatory Cosmetic Ingredients Listing on the product label

The Cosmetics Regulations will be amended to require listing of ingredients on cosmetic product labels. The Health Protection Branch (HPB) has received numerous requests from both consumers and health care professionals for all ingredients to be listed on cosmetic labels. This will allow consumers to avoid products containing ingredients to which they are sensitive and to allow physicians to more readily determine what ingredient has caused an allergic reaction in a patient.

The following represents the issues related to ingredient listing and how we are planning to address them.

Issue 1: Order of Declaration of Ingredients

The ingredients contained in cosmetic products may be indicated by either descending order of predominance or by alphabetical order. In the latter case, a statement indicating that the ingredients are listed by alphabetical order will be required.

If the ingredients are listed in descending order of predominance, the following alternatives will also be permitted:

All non-colour ingredients may be listed in descending order of predominance followed by all colours listed at random.

All non-colour ingredients present at a concentration of greater than 1% may be listed in descending order of predominance followed by all non-colour ingredients present at a concentration of 1% or less listed at random, followed by all colours listed at random.

An ingredient is defined in the following terms: Ingredients include any substances added to and present in the product, with the exception of "incidental ingredients".

Issue 2: Incidental Ingredients:

Incidental ingredients need not be identified on the label.

Incidental ingredients are defined in the following terms: Incidental ingredients are trace components of other ingredients or trace amounts of processing aids which are not intended to be present.

Examples of incidental ingredients include:

A processing aid which is added to a batch during manufacture and removed before the cosmetic is packaged, for example, filter aids.

A substance added to a cosmetic during manufacture and converted to an ingredient declared on the label, for example the addition of sodium hydroxide to form sodium stearate.

A substance added to a cosmetic at an insignificant level for its technical effect in processing, and which has no technical or functional effect in the finished product, for example a defoaming agent.

A substance added to a cosmetic ingredient and having no technical or functional effect in the finished product, for example a preservative agent in a cosmetic raw material, which due to its concentration in the finished product would no longer be effective.

Issue 3: Fragrances and Flavours:

Flavours and fragrances may be listed by the term "flavour" and "fragrance" and their chemical names need not be declared. They must appear in the declaration according to where they occur in terms of descending order of predominance (or alphabetical order). If an ingredient functions both as a flavour and a fragrance then both terms shall occur on the ingredient declaration unless the compound is identified by name. Any substance added to a cosmetic for another purpose but which also imparts a fragrance or a flavour may not be identified simply as "fragrance" or "flavour" but must be identified by its chemical name.

The term "flavour" is defined in the following terms:any ingredient or combination of ingredients in a cosmetic used solely to impart a taste to the cosmetic

The term "fragrance" is defined in the following terms: any ingredient or combination of ingredients in a cosmetic used solely to impart an odour to the drug (parfum)

Issue 4: Location/Nature of the Ingredient Declaration:

The ingredients will be listed on the outer label or, in the absence of an outer label, on the inner label. The ingredient declaration must be legible and conspicuous.

For containers where the total surface area available to bear labelling on the outermost package is less than 300 cm^2, or where the manufacturer wishes to use an ornamental container, the declaration of ingredients may appear on a firmly affixed tag, tape or card. For such products sold on trays or display stands, the declaration of ingredients may appear on a separate leaflet which must be presented or supplied in a packet attached to the display unit.

Issue 5: Use of the term "may contain" and/or the symbol "+/-" /Use of Common Labels:

Where a group of products is similar but not identical in composition and intended for the same use the ingredients may be declared as follows:

A list of the ingredients common to all the products, in cumulative descending order or alphabetical order, followed by either;

i) a list of the remaining ingredients identifying the specific products in which they occur; or

ii) the expression "may contain" and/or the symbol "+/-" followed by a declaration of ingredients which are not common in all of the products.

Similarly, in the case of a current or anticipated shortage of a cosmetic ingredient the declaration may specify alternatives to these ingredients, either immediately following the normally used ingredient and identified by the word "or", or following the declaration of all normally used ingredients, preceded by the phrase "may also contain" and/or the symbol "+/-". In the case where more than one alternative ingredient follows the expression "may also contain", these should be listed in descending order of expected predominance (or alphabetically).

Issue 6: The labelling of Professional Products:

For the purposes of this proposal no distinction is made between professional and consumer products. The labelling requirement is the same.

Issue 7: Free Samples and Testers:

Cosmetics which are distributed as free samples or supplied as testers are not required to carry an ingredient declaration.

Issue 8: Nomenclature:

Each ingredient shall be identified by the name adopted for that ingredient in the most recent edition and supplements of the CTFA Dictionary [International Cosmetic Ingredient Dictionary published by the Cosmetic, Toiletry and Fragrance Association Inc. (1101 17th Street, N.W., Suite 300, Washington, D.C. 20036. (Available from the Canadian Cosmetic, Toiletry, and Fragrance Association, 5090 Explorer Drive, Suite 510, Mississauga, Ontario, L4W 4T9].

In the absence of such listing in the CTFA Dictionary, the ingredient shall be listed according to standard international nomenclature methods, the chemical name, or other recognized technical name.

Botanicals and extracts of botanicals should be identified by the genus and species. The genus may be abbreviated.

Issue 9: Trade Secrets:

When an ingredient(s) is accepted as a trade secret and exempt from public disclosure, the phrase "and other ingredient(s)" may appear at the end of the ingredient declaration in lieu of label declaration of the identity of this ingredient(s).

A trade secret is defined in the following terms: A trade secret is "any ingredient(s) which is used in a product and which gives to the manufacturer an opportunity to obtain an advantage over competitors who do not know it or use it".

A manufacturer may petition for exemption from ingredient disclosure on the basis of a "trade secret". The petition will be evaluated on the basis of the following criteria:

i) The identity of the ingredient(s).

ii) The extent to which the identity of the ingredient is known outside the petitioner's business.

iii) The extent to which the identity of the ingredient is known by employees and others involved in the petitioner's business.

iv) The measures taken by the petitioner to guard the secrecy of this information.

v) The value of the information about the identity of the claimed trade secret ingredient to the petitioner and to its competitors.

vi) The amount of effort or money expended by the petitioner in developing the ingredient.

vii) The ease or difficulty with which the identity of the ingredient could be properly acquired or duplicated by others using contemporary, conventional analytical techniques.

viii) Confirmation that the identity of the ingredient has not been previously published or disclosed.

4.2. Revocation of Requirement for Cosmetic Notification

Given that there is no premarket authorization for the sale of cosmetics in Canada, and the degree of compliance with notification is unknown, the notification process does not appear to be the best mechanism to ensure the safety of cosmetics sold in Canada. When the *Cosmetics Regulations* are amended to require listing of ingredients on cosmetic product labels, the current notification requirements (Section 10 and 30 of the Cosmetics Regulations) will be revoked concurrently.

4.3. Annual registration

With the revocation of the mandatory notification, manufacturers and importers of cosmetic products will be required to register with the Drugs Programme annually. It is intended that this annual registration will represent a "right to sell" and will provide the Drugs Programme with the complete name and address of the manufacturers and importers of cosmetic products.

The registration will include a certification of awareness and compliance with the *Food and Drugs Act* and the *Cosmetics Regulations*, particularly that their products do not contain ingredients prohibited by the *Cosmetics Regulations*. The registration form will be signed by an authorized person from the company. This registration will be required under the revised Regulations. This annual registration will provide for the mechanism to recover the cost of the cosmetic programme probably through an annual fee for registration.

4.4. Cosmetic Ingredient Negative List

The Cosmetic Regulations will refer to Annex II, III and IV of the European Union, EEC Cosmetics Directives ("*List of substances which must not form part of the composition of cosmetic products*") and to sections of the United States Code of Federal Regulations, (but not

those dealing with "colour additives"), as amended from time to time, which prohibit or restrict the use of particular substances in cosmetics. These substances will likewise be prohibited or restricted as ingredients in cosmetics sold in Canada unless the *Cosmetics Regulations* specifically permit their use.

4.5. No Cosmetic Ingredient Positive List

A "positive list" of cosmetic ingredients will not be compiled. The administration of such a list would be extremely time and resource consuming and does not provide additional value to the assessment of the safety of products. Only those ingredients which are brought to our attention as being of a concern will be reviewed/assessed. There will be no provision for pre-market assessment of new ingredients. This is similar to the US approach.

4.6. Compliance programme

An efficient compliance programme will be in place to allow for investigation, product sampling and analysis. Reports on Drug Inspection Strategy and Drug Analytical Strategy are being taken into consideration in the development of the Compliance Programme.

4.6.1 Trade complaints and Enforcement priorities:

Industry has indicated its concern regarding compliance issues and requested that the Programme give higher priority to enforcement activities related to cosmetic products.

CCTFA has developed a Code of Marketing Practices and will recommend that manufacturers of cosmetic products comply with it. CCTFA has also developed a complaint resolution mechanism to deal with trade complaints. This mechanism should allow for improved compliance and enforcement since it would become a clear priority/responsibility for the Association. Information regarding these Association initiatives can be obtained from the Cosmetic, Toiletry, and Fragrance Association, 5090 Explorer Drive, Suite 510, Mississauga, Ontario, L4W 4T9.

CCTFA is requesting that the Drugs Programme develop performance standards to deal with the investigation/trade complaints, similar to those developed for the review of drugs. This would give them an assurance that the Drugs Programme is committed to enforce regulations and to take care of the violators. The Drugs Programme is currently working with CCTFA to develop appropriate performance standards for the handling of complaints.

4.6.2. Microbial Contamination

There is planned activity wherein products used in critical areas (such as area of the eye, face, mouth) are sampled. The current level is 200 samples in the Quebec region, and 50 in the other regions combined. Analytical activity has been primarily limited to unscheduled samples resulting from an investigation or consumer complaints.

Industry has requested that the sampling program be continued. Products containing low levels or no preservatives should also be included in the sampling program. With ingredient listing, these products will be easily identifiable by the inspectors.

4.6.3 Consumer complaints

The bulk of the work done by the regions arises from consumer complaints of adverse reactions or from complaints which are more suited to drugs. These always result in an investigation and sometimes with sampling for microbial and ingredient analysis. The extent of the investigation depends on the region's assessment of the situation.

After consultation with CCTFA and Drugs Programme representatives, it was decided that the responsibility of responding to consumer complaints should continue to rest within the Drugs Programme. It was suggested that perhaps, industry can provide guidance to member companies and to consumers as to what are the steps that should be taken to register a complaint, i.e., contact the closest Health Protection Branch office, manufacturer, etc.

A policy is being developed to clarify roles and responsibilities of all concerned, analogous to the Drugs Programme Roles and Responsibilities document on advertising.

4.6.4 Health Hazard Assessment (HHA)

The number of health hazard assessments (HHA) for cosmetic products is about 10 per year. They come directly from the regions and from the Compliance and Liaison Division (CLD). Most of the time they are the result of consumer adverse effects after using cosmetic products or due to microbial contamination. The responsibility for the HHA should remain within the Drugs Programme.

5. IMPLEMENTATION

In order to fully implement the proposed regulatory framework, a number of changes are required to be made to the *Cosmetics Regulations* to the *Food and Drugs Act*. Until such time as the appropriate changes to the Regulations are made, manufacturers are required to continue to submit notification as per Section 10 and 30 of the current Regulations. All other aspects of the *Cosmetics Regulations* also continue to apply and manufacturers are responsible to ensure that they comply with these Regulations.